CLAIMS

1. A method for producing osseoinductive extracellular material from skeletal cells which method comprises or consists of the steps of:

(1) culturing skeletal cells in a suitable culture medium;

(2) harvesting extracellular material produced by said cultured cells; and optionally isolating and/or purifying said harvested material;

(3) lyophilyzing said material; and

(4) irradiating said material with gamma radiation.

2. A method according to claim 1 including the additional step of adding a radioprotectant moiety to the material prior to said irradiating step (4).

3. A method according to claim 1 wherein the material contains a radioprotectant moiety prior to said irradiating step (4).

4. A method according to claim 1 or 2 or 3 including the additional step of:

(5)adding a physiologically acceptable diluent and/or excipient and/or adjuvant and/or carrier, to form a therapeutic composition.

5. A material produced by the method of claim 1 or 2 or 3.

6. A material according to claim 5 which is substantially free of bacteria and viruses.

7. A composition produced by the method of claim 4.

8. A composition according to claim 7 which is substantially or completely free of bacteria and viruses.

9. A method of treating a patient (human or other animal) requiring bone repair/regeneration, which involves administering to said patient an osseoinductive amount of a material according to claim 5 or 6.

10. A method of treating a patient (human or other animal) requiring bone repair/regeneration, which involves administering to said patient an osseoinductive amount of a composition according to claim 6 or 7.

11. Use of a material according to claim 5 or 6 in a method of manufacture of a therapeutic biological osseoinductive medicament for bone repair/regeneration.

12. Use of a composition according to claim 7 or 8 in a method of manufacture of a therapeutic biological osseoinductive medicament for bone repair/regeneration.

13. A composition according to claim 7 or 8 in frozen form.

14. A composition according to claim 7 or 8 in frozen-thawed form.

15. A composition according to claim 7 or 8 in freeze-dried form.

16. A method according to claims 1 to 4 wherein said material is obtained from cartilage cells.

17. A method according to claim 16 wherein said material is obtained from hypertrophic cartilage cells.

18. A method according to claim 17 wherein said material is obtained from immortalised hypertrophic chondrocyte cells.

19. A method according to claims 16 to 18 wherein said material is obtained from a human cell.

20. A method according to claim 19 wherein said material is obtained from a human cell line.

21. A method according to claims 1 to 4 wherein said material contains a mixture of: (1) one or more cytokine; (2) one or more growth factor; and (3) one or more collagen.

22. A method according to claim 2 or 3 wherein said radioprotectant moiety comprises or consists of a free radical scavenger.

23. A method according to claim 2 or 3 wherein said radioprotectant moiety comprises or consists of an anti-oxidant.

24. A method according to claims 1 to 4 wherein said irradiating step (4) is at a dose in the range 100Gy to 45kGy.

25. A method according to claims 1 to 4 wherein said irradiating step (4) is at a dose in the range 5kGy to 45kGy.

26. A method according to claims 1 to 4 wherein said irradiating step (4) is at a dose in the range 5kGy to 20kGy.

27. A method according to claims 1 to 4 wherein said irradiating step (4) is at a dose selected from the group consisting of 5kGy, 10kGy, 15kGy, and 20kGy.

28. A method according to claims 1 to 4 wherein said irradiating step (4) is carried out at a temperature in the range -30°C to +80°C.

29. A method according to claims 1 to 4 wherein said irradiating step (4) is carried out at about room temperature.

30. A method according to claims 1 to 4 wherein said irradiating step (4) is carried out at or below room temperature.

31. A method according to claims 1 to 4 wherein said irradiating step (4) is carried out at or above room temperature.

32. A method of treatment according to claim 9 or 10 wherein said osseoinductive material or composition is used in conjunction with a medical device, whereby the material promotes/augments supplemental bone formation in, on or around the device.

33. A method of treatment according to claim 9 or 10 wherein said osseoinductive material or composition is administered for bone repair/regeneration in a medical indication selected from the group consisting of: bone fractures; surgical bone loss e.g. resulting from removal of cancerous bone, craniomaxillofacial surgery and cranioplasty; joint revision including hip, knee, shoulder, and small joint replacements;bone trauma

including all orthopaedic and craniomaxillofacial fractures e.g. spinal fusion following laminectomy inclusive of total disc prosthesis and nuclear prosthesis; osteoporetic fractures and bony spinal injury; congenital bone defects e.g. osteogenesis imperfecta; bone structures requiring supplementation such as bone void filling e.g. following a craniotomy; osteoporosis; and periodontal defects such as oral and periodontal repair including the filling of intrabony voids and alveolar ridge augmentation and voids in the jawbone; periodontal repair of alveolar bone and preparation of alveolar bone for implants and prostheses; and supplementation/augmentation of bone formation in combination with prostheses, including joints (hip, knee, ankle, elbow), dental implants, maxilliofacial devices and spine devices.

34. Use of a material or composition according to claims 11 or 12 in a method of manufacture of a therapeutic biological osseoinductive medicament for bone repair/regeneration in a medical indication selected from the group consisting of: bone fractures; surgical bone loss e.g. resulting from removal of cancerous bone, craniomaxillofacial surgery and cranioplasty; joint revision including hip, knee, shoulder, and small joint replacements;bone trauma including all orthopaedic and craniomaxillofacial fractures e.g. spinal fusion following laminectomy inclusive of total disc prosthesis and nuclear prosthesis; osteoporetic fractures and bony spinal injury; congenital bone defects e.g. osteogenesis imperfecta; bone structures requiring supplementation such as bone void filling e.g. following a craniotomy; osteoporosis; and periodontal defects such as oral and periodontal repair including the filling of intrabony voids and alveolar ridge augmentation and voids in the jawbone; periodontal repair of alveolar bone and preparation of alveolar bone for implants and prostheses; and supplementation/augmentation of bone formation in combination with prostheses, including joints (hip, knee, ankle, elbow), dental implants, maxilliofacial devices and spine devices.

35. An irradiated osseoinductive extracellular material from skeletal cells, wherein said material is "Skeletex^{TM}".

36. A lyophilised irradiated osseoinductive extracellular material from skeletal cells, wherein said material is "Skeletex^{TM}".